U.S. ARMY RESEARCH OFFICE

BROAD AGENCY ANNOUNCEMENT

W911NF-05-R-0011

2006 Medical Science and Technology (S&T) Chemical and Biological Defense Transformational Medical Technologies Initiative Fund (TMTIF)

August 2005

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I. INTRODUCTION

On 22 April 2003, the Undersecretary of Defense, Acquisition, Technology and Logistics (USD(AT&L)) approved the "Implementation Plan for the Management of the Department of Defense Chemical and Biological Defense Program." The plan defines the roles and responsibilities and provides the implementation procedures for CBDP management. The CBDP provides for planning, programming, budgeting and execution of the Chemical/Biological/ Radiological/Nuclear (CBRN) defense research, development and acquisition; programming and budgeting for CBD equipment, sustainment, and training; establishing military requirements for CBRN defense; and test and evaluation of CBRN defense programs.

The purpose of this Broad Agency Announcement (BAA) is to solicit proposals for the Department of Defense (DoD) Fiscal Year 2006 Medical Science and Technology (S&T) Chemical and Biological Defense Transformational Medical Technologies Initiative Fund (TMTIF). The DoD conducts a vigorous medical research program in chemical and biological defense with the goal of protecting the warfighter from disease and biological and chemical warfare agents. The CBDP seeks to develop counter-measures that can be brought into acquisition and fielded worldwide. These products must be regulatory compliant, robust, and highly effective at a reasonable cost. Successful candidates must have a clear path to regulatory approval, production and end user utility. They must all be amenable to use in a military environment.

This BAA is focused on developing medical counter-measures to genetically engineered or non-traditional toxins, virulence factors and microorganisms as biological warfare (BW) threat agents. This includes a faster bug-to-drug approach. It is anticipated that these counter-measures would include pre-treatments (including vaccines), therapeutics and basic science to characterize the nature of the threat and identify key targets for intervention or disruption of these agents. The agent classes that are to be focused on are: intra-cellular bacterial pathogens, hemorrhagic fever viruses and bioregulators.

Approaches to the objectives for this area include studying the genetic diversity and pathogenicity of natural isolates, identifying common structural elements of specific agents or classes of agents (preferred), elucidating common virulence mechanisms (such as type III secretory proteins), identifying functional domains in toxins and virulence factors, and using this information to develop rapid and effective medical countermeasures protecting against genetically engineered or emerging BW threats.

II. FUNDING OPPORTUNITY DESCRIPTIONS

A. Overview

Proposals are being sought in basic, applied, and advanced development in the following research areas:

Basic Research:

1. Identify primary or common host pathways/networks that respond to pathogenesis events for the initially selected pathogen groups and/or multiple category A/B/ and C agents to evaluate potential intervention points for broad-spectrum therapeutic approaches.

2. Develop systems biology tools to analyze complex biological functions at the level of gene expression, biochemical and metabolic pathways, gene and protein structures to discover and validate novel biomarkers, drugs and future broad-spectrum drug targets.

3. Identify primary or common host pathways/networks that respond to pathogenesis events for the initially selected pathogen groups and/or multiple category A/B/ and C agents to evaluate potential intervention points for broad-spectrum therapeutic approaches

4. Exploit advances in genomics, proteomics, metabolomics (metabolic profiling) and systems biology studies to identify pathogenesis and host response pathways and networks for classes of pathogenic mechanisms.

5. Develop in silico methodologies to predict three-dimensional structure and comparative assessment of virulence moieties on important protein virulence molecules.

6. Determine feasibility of re-directing host cellular response patterns that have been compromised by pathogen-directed shifts in pathways (e.g. override of host apoptosis pathways,

immune down-regulation, signal transduction agonists / antagonists, etc.) for protection and/or to restore health.

Applied Research:

1. Develop computer-based technologies that enable the development of small molecule medical countermeasure candidates based upon structure/function analysis of either BW agent or host response pathway target, in order to reduce the drug development timeline through parallel processing, tool interoperability and accessible information sources.

2. Develop sophisticated ex-vivo cell-based model systems (replicating target tissues) (e.g., organ culture, transplant models/transgenic models) to replace animal models in the study of medical countermeasure bioactivity, efficacy and safety.

Advanced Research:

1. Drug discovery efforts in cutting-edge nucleic acid based therapies such as anti-sense and RNA interference technology that target common bacterial virulence or house-keeping genes (pathogenicity islands, quorum-sensing molecules, siderophores, etc.)

2. Develop high throughput proteomics and metabolomics multiplex platforms to parallel process multiple samples to generate informative knowledge based systems for bug-to-drug target development and validation.

3. Investigate to develop new processes and systems for drug development to reduce drug development timelines through parallel processing of multiple drug candidates.

4. Develop new or adapt existing small molecule compounds for therapeutic intervention against common pathogenesis pathways.

III. INFORMATION FOR OFFERORS

The solicitation is specifically for experimental and theoretical development of technologies for chemical and biological defense as described in Section II. Potential offerors are advised to read this announcement carefully. It explains the agencies' research needs upon which the topic is based and the terms and conditions of the solicitation.

A. General Information

Through this solicitation the DoD CBDP and the Army Research Office (ARO) expect to make several awards for one- to two-year performance periods, subject to the availability of appropriations. Awards may be made as contracts or grants. Single-year, stand-alone proposals are encouraged; multi-year proposals will be considered. A total of up to approximately $63 million is anticipated to be available under this solicitation. It is anticipated that funding will be between $1M to $4M per award.

B. Eligibility

Proposals may be submitted by degree-granting universities, nonprofit organizations, or industrial concerns. Proposals are encouraged from Historically Black Colleges and Universities (as determined by the Secretary of Education to meet requirements of Title III of the Higher Education Act of 1965, as amended (20 U.S.C. § 1061)) and from Minority Institutions defined as institutions "whose enrollment of a single minority or a combination of minorities…exceeds 50 percent of the total enrollment." [20 U.S.C. § 1067k(3) and 10 U.S.C. § 2323(a)(1)(C)].

Federal laboratories, Federally Funded Research and Development Centers, and academic institutions that are federal government organizations (e.g., Naval Postgraduate School) can submit to the separate federal program for support, but are not be eligible to receive funding from this solicitation. They are encouraged to contact the technical point of contact listed in Section III.G. for information on how to submit to the internal research program.

C. Military Recruiting

This is to notify potential offerors that each grant awarded under this announcement to an institution of higher education shall include the following term and condition:

"As a condition for receipt of funds available to the Department of Defense, under this award, the recipient agrees that it is not an institution of higher education (as defined in 32 Code of Federal Regulations (CFR) Part 216) that has a policy of denying, and that it is not an institution

of higher education that effectively prevents, the Secretary of Defense from obtaining for military recruiting purposes: (A) entry to campuses or access to students on campuses; or (B) access to directory information pertaining to students. If the recipient is determined, using procedures in 32 CFR Part 216 to be such an institution of higher education during the period of performance of this agreement, and therefore to be in breach of this clause, the Government will cease all payments of DoD funds under this agreement and all other DoD grants and cooperative agreements, and it may suspend or terminate such grants and agreements unilaterally for material failure to comply with the terms and conditions of award." (32 CFR Part 216 may be accessed electronically at http://www.gpoaccess.gov/cfr/index.html.)

If your institution has been identified under the procedures established by the Secretary of Defense to implement Section 558 of Public Law 103-337, then: (1) no funds available to DoD may be provided to your institution through any grant, including any existing grant; (2) as a matter of policy, this restriction also applies to any cooperative agreement; and (3) your institution is not eligible to receive a grant or cooperative agreement in response to this solicitation.

This is to notify potential offerors that each contract awarded under this announcement to an institution of higher education shall include the clause: Defense Federal Acquisition Regulation Supplement (DFARS) 252.209-7005, Reserve Officer Training Corps and Military Recruiting on Campus.

D. Protection of Human Subjects

All research under this contract involving human subjects must be conducted in accordance with 32 CFR 219, 10 USC 980, and DoDD 3216.2, as well as other applicable federal and state regulations. Contractors must be cognizant of and abide by the additional restrictions and limitations imposed on the DoD regarding research involving human subjects, specifically as regards vulnerable populations (32 CFR 219 modifications to subparts B-D of 45 CFR 46), recruitment of military research subjects (32 CFR 219), and surrogate consent (10 USC 980).

Defense Threat Reduction Agency (DTRA) Directive 3216.01 establishes the DTRA Human Subjects Protection Program, sets forth the policies, defines the applicable terms, and delineates the procedures necessary to ensure DTRA compliance with federal and DoD regulations and legislation governing human subject research. The regulations mandate that all DoD activities, components, and agencies protect the rights and welfare of human subjects of study in DoD-supported research, development, test and evaluation, and related activities hereafter referred to as "research". The requirement to comply with the regulations applies to new starts and to continuing research.

The DTRA directive requires that research using human subjects may not begin or continue until the DTRA's Human Research Oversight Board (HROB) has reviewed and approved the proposed protocol. Contractors and subcontractors are required to submit a valid federal assurance for their organization (institution, laboratory, facility) that has been issued by either DoD or the Department of Health and Human Services, and documentation of review of proposed protocols by the local Institutional Review Board (IRB) to include consent forms for any planned research using human subjects to the DTRA HROB for its review through the contracting officer's representative (if assigned) or the contracting officer. The HROB review is separate from, and in addition to, local IRB review.

Written approval to begin research or subcontract for the use of human subjects under the proposed protocol will be provided in writing from the DTRA HROB, through the contracting officer. Both the contractor and the government shall maintain a copy of this approval. Any proposed modifications or amendments to the approved protocol or consent forms must be submitted to the local IRB and the DTRA HROB for review and approval. Examples of modifications/amendments to the protocol include but are not limited to:

1) a change of the Principal Investigator;
2) changes in duration or intensity of exposure to some stimulus or agent;
3) changes in the information requested of volunteers, or changes to the use of specimens or data collected; or

4) changes in perceived or measured risks or benefits to volunteers that require changes to the study.

Research pursuant to such modifications or amendments shall not be initiated without IRB and HROB approval except when necessary to eliminate apparent and immediate hazards to the subject(s).

Research projects lasting more than one year require IRB review at least annually, or more frequently as required by the responsible IRB. HROB review and approval is required annually. The contractor or subcontractor must provide documentation of continued IRB review of protocols for HROB review and approval in accordance with the Contract Data Requirements List. Research must not continue without renewed HROB approval unless necessary to eliminate apparent and immediate hazards to the subject(s).

Non-compliance with any provision of this clause may result in withholding of payments under the contract pursuant to the contract's payments clause(s) and/or contract termination pursuant to the contract's termination clause(s). The government shall not be responsible for any costs incurred for research involving human subjects prior to protocol approval by the HROB.

E. Animal Use

The DOD Directive 3216.1, dated April 17, 1995, provides policy and requirements for the use of animals in DOD-funded research. The DoD definition of animal is any live nonhuman vertebrate. All proposals that involve the use of animals must address DoD compliance with Directive 3216.1.

For animals, the provisions include rules on animal acquisition, transport, care, handling, and use in: (i) 9 CFR parts 1-4, Department of Agriculture rules that implement the Laboratory Animal Welfare Action of 1966 (U.S.C. 2131-2156); and (ii) the "Guide for the Care and Use of Laboratory Animals," National Institutes of Health Publication No. 86-23.

F. Biological Defense Research Program (BDRP) Requirements

Applicable to the BDRP funded awards. For those institutions where Principal Investigators are supported by the USAMRMC and are conducting research with Bio-safety Levels 3 and 4 material, a Facility Safety Plan must be prepared in accordance with 32 Code of Federal Regulations (CFR) 626.18. See URL: www.access.gpo.gov/nara/cfr/waisidx_99/32cfr626_99.html for a copy of 32 CFR 626.18, Biological Defense Safety Program.

G. Points of Contact

Technical point of contact for this BAA is Dr. Stephen J. Lee, Chemical Sciences Division, (919) 549-4365, email: stephen.lee2@us.army.mil. Questions regarding the administrative content of this BAA may be addressed to ARO at (919) 549-4375.

H. Department of Defense (DoD) Central Contractor Registration (CCR)

Prospective contractors/grantees must be registered in the DoD CCR database prior to award of an agreement. By submission of an offer resulting from this BAA, the offeror acknowledges the requirement that a prospective contractor/grantee must be registered in the CCR database prior to award, during performance, and through final payment of any agreement resulting from this BAA. The CCR may be accessed at http://www.ccr.gov/. Assistance with registration is available by phone at 1-888-227-2423.

I. Reporting Requirements

Reporting requirements for contracts and grants awarded under this BAA will be as described in ARO Form 18 located at ~~http://www.aro.army.mil/forms/forms2.htm.~~ Additional reports will be specified in the award document.

IV. APPLICATION AND SUBMISSION INFORMATION

A. Application and Submission Process

This solicitation will be conducted in two stages as follows:

Stage I – Interested offerors are required to submit white papers in accordance with instructions provided in Section IV.B. of this BAA. White papers will be evaluated against criteria in Section V.A. of this BAA. Based on this evaluation, selected offerors will be invited to submit full proposals for evaluation under Stage II.

Stage II – Selected offerors invited to submit full proposals under Stage I will submit proposals in accordance with the instructions provided in Section IV.C. of this BAA. Full proposals will be evaluated against criteria in Section V.B. of this BAA.

B. Stage I - White Paper Submission and Content

Interested offerors are required to submit a white paper consisting of a quad chart and a 1-3 page narrative to expand on the quad chart. The white paper must be received by 4:00 PM local time, October 11, 2005. The white paper must be transmitted electronically to the following address: **whitepapers@arl.army.mil**. The e-mail subject line should contain the following: W911NF-05-R-0011 White Paper.

Each submission (quad chart and narrative) must specify a single topic area and issues for consideration by identifying at the end of the project title the specific paragraph referenced in Section ~~II.B.~~ of this BAA (for example, II.B.1.c). See quad chart format and narrative guidelines below.

Quad Chart Format:

Title of Project, Submitting Principal Investigator, Organization, BAA Number,

Objective: Clear, concise (1-2 sentence) description of the goal of the effort (Arial 12 point) **Description of Effort: Brief description of the technology proposed for investigation and methodologies to be used during the course of investigation (Arial 12 pt)**	**Picture or graphic** **that illustrates the technology or concept**
Benefit to warfighter: Brief statement of capability enhancement resulting from successful completion with respect to the Baseline Capability Assessment (BCA) (Arial 12 pt) **Challenges: A bullet list of the technical or scientific challenges being addressed (Arial 12 pt)** **Maturity of Technology: Describe the maturity of the proposed technology with respect to the Technical Readiness Level (TRL) *(Arial 12 pt)**	**Major goals/milestones by fiscal year:** **•Bullet list (Arial 12 pt)** **Proposed Funding ($K):** **Deliverables** **PI contact info: Dr. Marge N. Overra, (123) 123-1234, Marge.N.Overra@innovationsrus.com**

*See Attachment 1 to this BAA for Technology Readiness Level (TRLs) for Chemical Biological Defense Programs.

The narrative expanding on the quad chart shall not exceed three pages, 8.5 x 11 inches, single-spaced, with one-inch margins in type not smaller than 12 points. The project title with topic paragraph referenced in Section II must be included at the top of the page and the narrative must have the full contact information for the principal investigator. The content of the narrative must be limited only to further explanation, as deemed necessary by the offeror, of the information being conveyed as requested in the quad chart. Do NOT include corporate or personnel qualifications, past experience, or any supplemental information not requested in the Quad Chart.

The narrative must contain the following information:

1. Principal investigator name, laboratory/facility, mailing address, telephone and facsimile and e-mail address
2. Project title

3. Is the proposal submitted from a Federal laboratories, Federally Funded Research and Development Centers or academic institutions that are federal government organizations (e.g., Naval Postgraduate School)? Mark *Yes* or *No*. If yes, note the name of the facility.
4. From Section II, the reference paragraph (Basic, Applied or Advanced Research) and the specific topic area under the reference paragraph that the research will address (e.g., Advanced Research, #4 - Develop compounds small molecules for therapeutic intervention against common pathogenesis pathways).
5. Project objective
6. Methods
7. Milestones
8. Preliminary data
9. Intended accomplishments (deliverables)
10. Estimated project start date
11. Estimated project end date

Feedback on the white papers and invitations to submit full proposals for selected white papers will be e-mailed directly to the proposed Principal Investigators not later than November 4, 2005.

C. Stage II - Full Proposal Submission and Content

1. Proposal Submission

Proposals will be accepted from invited offerors. Proposals must be submitted electronically and must contain all information specified in Proposal Content below. The electronic proposal must be received at the Army Research Office by 4:00 PM local time on January 3, 2006.

Proposals must be transmitted to the following address: baa@arl.army.mil. Proposals must be submitted in a single PDF formatted file. The e-mail subject line should contain the following: W911NF-05-R-0011 Proposal.

The proposal shall contain three electronic forms: (1) ARO Form 51, Proposal Cover Page; (2) ARO Form 99, Summary Proposal Budget; and (3) ARO Current and Pending Support

(unnumbered form). See Proposal Content below. These forms may be accessed electronically at http://www.aro.army.mil/forms/forms2.htm. The fillable PDF forms may be saved to a working directory on your computer and opened and filled in using the Adobe Acrobat software application. The fillable Proposal Cover Page (ARO Form 51) should be printed, signed, and scanned into a PDF file with the proposal.

If you have questions concerning electronic proposal submission, please contact the Army Research Office at (919) 549-4219. Proposals submitted by facsimile will not be accepted.

Proposals received after the deadline will be handled in accordance with the provisions detailed in Section IV.E. of this BAA. Acknowledgment of receipt of a proposal under this solicitation will be accomplished via e-mail to the addressee submitting the proposal.

2. Proposal Content

The full proposal should be broken down into two volumes: Volume I – Technical Proposal, and Volume 2 – Cost Proposal.

Volume I - Technical Proposal The technical proposal shall not exceed 25 pages. A page is defined as 8 ½ x 11 inches, single-spaced, with one-inch margins, and type not smaller than 12 points. The technical proposal must include the following components:

a) Cover page. To be eligible for review, proposals must have a completed and signed ARO Form 51 as a cover page (See Section IV.C.1. of this BAA). Under the title, cite, from Section II, the reference paragraph (Basic, Applied or Advanced Research) and the specific topic area under the reference paragraph that the research will address (e.g., Advanced Research, #4 - Develop small molecule compounds for therapeutic intervention against common pathogenesis pathways). In Block 2 on the Proposal Cover Page, check “Chemistry.” In Block 19 on the Proposal Cover Page, check “Other” and specify “CBDP.”

b) Summary page with the proposal title, the principal investigator(s), institution affiliation and a brief summary/abstract of the proposal (1 page). The summary page must also include the following sentence and the answer: "*Is the proposal submitted from a Federal laboratories, Federally Funded Research and Development Centers or academic institutions that are federal government organizations (e.g., Naval Postgraduate School)?*" Answer *Yes* or *No*. If yes, note the name of the facility.

c) Objective, background and significance. A description of the objective, significance and applicability of the proposed research, appropriate scientific background, and a concise description of the advantages gained from the proposed technology (not to exceed 6 pages).

d) Work to be performed. A detailed list that describes major tasks and supporting subtasks, expected results of each major task, and how the task will be accomplished (not to exceed 8 pages).

e) Proposed schedule, milestones, and deliverables – technical and financial reports, data, hardware, software and documentation, as applicable (not to exceed 2 pages).

f) Summary of qualifications of key personnel (not to exceed 1 page per person).

g) Describe the facilities available for accomplishment of research objective. Describe the equipment planned for acquisition under this program and its application to the objective. When possible, equipment should be purchased very early in the research award period.

h) Statement of Current and Pending Support. A statement of current and pending support must be included for each investigator listed in the proposal. Use the ARO Current and Pending Support form to submit this information (See Section IV.C.1. of this BAA). This statement requires that each investigator specify all grants and contracts through which he or she is currently receiving or may potentially receive financial support.

NOTE: Failure to provide the requested information or exceed page limits may render the proposal non-responsive, and the proposal may not be evaluated.

Volume II – Cost Proposal

The financial portion of the proposal should contain cost estimates sufficiently detailed for meaningful evaluation. Use ARO Form 99, Summary Proposal Budget, to submit budget data (See Section IV.C.1. of this BAA). For budget purposes, use an award start date of May 1, 2006. The budget must include the total cost of the project, as well as a breakdown of the amount(s) by source(s) of funding (e.g., funds requested under this BAA, non-federal funds to be provided as cost sharing). The cost proposal is not considered part of the page count; there is no page limit for the cost proposal.

Budgeted cost elements should reflect the following:

a) Time being charged to the project, for whom (principal investigator, graduate students, etc.), and the commensurate salaries and benefits. Allowable charges for graduate students include salary, appropriate research costs, and tuition. Allowable

charges for undergraduate students include salary and research training costs, but not tuition.

b) Cost of equipment, based on most recent quotations and broken down in sufficient detail for evaluation.

c) Travel costs and time, and the relevance to stated objectives.

d) Estimate of material and operating costs.

e) Publication and report costs.

f) Consultant fees (indicating daily or hourly rate) and travel expenses and the nature and relevance of such costs.

g) Computer services.

h) Sub-award costs and type (the portion of work to be sub-awarded and rationale). Include detailed cost summary.

i) Communications costs not included in overhead.

j) Other direct costs.

k) Indirect costs.

l) Fee, if any, which an industrial/commercial organization proposes.

m) Facilities Capital Cost of Money: When an offeror elects to claim facilities capital cost of money as an allowable cost, the offeror should submit Form CASB-CMF and show the calculation of the proposed amount. (See FAR 31.205-10.)

NOTE: Failure to provide the requested information may render the proposal non-responsive, and the proposal may not be evaluated.

D. Marking of White Paper and Proposal and Disclosure of Proprietary Information Outside the Government

1. The white paper/proposal submitted in response to this solicitation may contain technical and other data that the offeror does not want disclosed to the public or used by the Government for any purpose other than proposal evaluation. Public release of information in any white paper/proposal submitted will be subject to existing statutory and regulatory requirements. If proprietary information which constitutes a trade secret, proprietary commercial or financial information, confidential personal information, or data affecting the national security, is provided by an offeror in a white paper/proposal, it will be treated in confidence, to the extent permitted by law, provided that the following legend appears and is completed on the front of the white paper/proposal: "For any purpose other than to evaluate

the white paper/proposal, this data shall not be disclosed outside the Government and shall not be duplicated, used, or disclosed in whole or in part, provided that if an award is made to the offeror as a result of or in connection with the submission of this data, the Government shall have the right to duplicate, use or disclose the data to the extent provided in the agreement. This restriction does not limit the right of the Government to use information contained in the data if it is obtained from another source without restriction. The data subject to this restriction is contained in page(s) ____ of this white paper/proposal." Any other legend may be unacceptable to the Government and may constitute grounds for removing the proposal from further consideration without assuming any liability for inadvertent disclosure. The Government will limit dissemination of properly marked information to within official channels. In addition, the pages indicated as restricted must be marked with the following legend: "Use or disclosure of the white paper/proposal data on lines specifically identified by asterisk (*) are subject to the restriction on the front page of this white paper/proposal." The Government assumes no liability for disclosure or use of unmarked data and may use or disclose such data for any purpose.

2. In the event that properly marked data contained in a white paper/proposal submitted in response to this BAA is requested pursuant to the Freedom of Information Act, 5 USC 552, the offeror will be advised of such request and, prior to such release of information, will be requested to expeditiously submit to ARO a detailed listing of all information in the white paper/proposal which the offeror believes to be exempt from disclosure under the Act. Such action and cooperation on the part of the offeror will ensure that any information released by ARO pursuant to the Act is properly determined.
3. By submission of a white paper/proposal, the offeror understands that proprietary information may be disclosed outside the Government for the sole purpose of technical evaluation. The ARO/RDECOM Acquisition Center will obtain a written agreement from the evaluator that proprietary information in the white paper/proposal will only be used for evaluation purposes and will not be further disclosed or utilized.

E. Late Submissions and Withdrawal of Proposals

1. Offerors are responsible for submitting electronic proposals so as to reach the Government office designated in this BAA by the time specified in this BAA.

2. If the electronic proposal is received at the Government office designated in this BAA after the exact time and date specified for receipt of offers, it is "late" and will not be considered unless it was received at the initial point of entry to the Government infrastructure not later than 4:00 PM local time one working day prior to the date specified for receipt of proposals.

3. Acceptable evidence to establish the time of receipt at the Government office includes documentary evidence of receipt maintained by the installation.

4. If an emergency or unanticipated event interrupts normal Government processes so that proposals cannot be received at the office designated for receipt of proposals by the exact time specified in the solicitation, and urgent Government requirements preclude amendment of the solicitation closing date, the time specified for receipt of proposals will be deemed to be extended to the same time of day specified in the solicitation on the first work day on which normal Government processes resume.

5. Proposals may be withdrawn by written notice received at any time before award. Withdrawals are effective upon receipt of notice by the Contracting Officer.

V. EVALUATION CRITERIA AND SELECTION PROCESS

The white paper and proposal selection process will be conducted based upon a technical peer review as described in Federal Acquisition Regulation Subparts 6.102(d)(2) and 35.016 and DOD Grant and Agreement Regulations (DOD 3210.6-R (DODGARS), Section 22.315. All information necessary for the review and evaluation of the white paper and proposal must be contained in the White Paper and Full Proposal submissions as described in Sections IV.B. and IV.C. of this BAA. The evaluation criteria to be used to evaluate and select white papers and proposals are listed below:

A. White Paper (Stage I).

The evaluation will be based on the following criteria, which are weighted:

1. Scientific merit and technical approach (90%)
2. Applicability to the BAA thrust area (10%)

B. Full Proposal (Stage II).

The first tier is a scientific peer review of proposals against established criteria for determination of scientific merit. These reviews provide unbiased, expert advice on the scientific and technical merit of proposals, based upon the following review criteria, which are weighted as follows:

1. Research strategy and objectives (50%)
2. Impact (30%)
3. Principal Investigator and key personnel qualifications (5%)
4. Facilities (5%)
4. Budget (10%)

The peer review summary statement is a product of scientific peer review. Each statement includes the investigator 's structured, technical abstract and an evaluation of the project as assessed by the peer reviewers according to the above evaluation criteria. Summary statements are forwarded to the next stage of the review process, the programmatic review.

The second tier of review, the programmatic review, is conducted by a team of military scientists, researchers and/or other federal agency representatives. Panel members use the peer review summary statements to make funding recommendations. Programmatic review uses the following four criteria to make their recommendations:

1. Peer review recommendations
2. Relevance of proposed research to military programs
3. Programmatic priorities
4. Portfolio balance

Scientifically sound proposals that best fulfill the above criteria and most effectively address the unique focus and goals of the DoD CBDP will be recommended for funding.

VI. NOTIFICATION TO OFFERORS

Notification of acceptance of full proposals will be mailed or e-mailed by ARO on or about April 3, 2006. Unsuccessful offerors will be notified shortly thereafter.

VII. INFORMATION TO BE REQUESTED FROM SUCCESSFUL OFFERORS

Offerors whose proposals are accepted for funding will be contacted before award to provide additional information required for award. This may include representations and certifications, revised budgets or budget explanations, certificate of current cost or pricing data, subcontracting plan for small businesses, and other information as applicable to the proposed award.

VIII. CERTIFICATIONS REQUIRED FOR GRANT AWARDS

A. Certification at Appendix A to 32 CFR Part 28 Regarding Lobbying

By signing and submitting a proposal that may result in the award of a grant exceeding $100,000, the prospective awardee is certifying, to the best of his or her knowledge and belief, that:

(1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of an agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.

(2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of

Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.

(3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify and disclose accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty or not less than $10,000 and not more than $100,000 for each such failure.

B. Certification at Appendix A to 32 CFR Part 25 Regarding Debarment, Suspension, and Other Responsibility Matters --Primary Covered Transactions

(1) By signing and submitting this proposal, the prospective primary participant is providing the certification set out below.

(2) The inability of a person to provide the certification required below will not necessarily result in denial of participation in this covered transaction. The prospective participant shall submit an explanation of why it cannot provide the certification set out below. The certification or explanation will be considered in connection with the department or agency's determination whether to enter into this transaction. However, failure of the prospective primary participant to furnish a certification or an explanation shall disqualify such person from participation in this transaction.

(3) The certification in this clause is a material representation of fact upon which reliance was placed when the department or agency determined to enter into this transaction. If it is later determined that the prospective primary participant knowingly rendered an erroneous

certification, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

(4) The prospective primary participant shall provide immediate written notice to the department or agency to which this proposal is submitted if at any time the prospective primary participant learns that its certification was erroneous when submitted or has become erroneous by reason of changed circumstances.

(5) The terms "covered transaction," "debarred,”" suspended," "ineligible," "lower tier covered transaction," "participant," "person," "primary covered transaction," "principal," "proposal," and "voluntarily excluded," as used in this clause, have the meanings set out in the Definitions and Coverage sections of the rules implementing Executive order 12549. You may contact the department or agency to which this proposal is being submitted for assistance in obtaining a copy of those regulations.

(6) The prospective primary participant agrees by submitting this proposal that, should the proposed covered transaction be entered into, it shall not knowingly enter into any lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, declared ineligible, or voluntarily excluded from participation in this covered transaction, unless authorized by the department or agency entering into this transaction.

(7) The prospective primary participant further agrees by submitting this proposal that it will include the clause titled "Certification Regarding Debarment, Suspension, Ineligibility and Voluntary Exclusion--Lower Tier Covered Transaction," provided by the department or agency entering into this covered transaction, without modification, in all lower tier covered transactions and in all solicitations for lower tier covered transactions.

(8) A participant in a covered transaction may rely upon a certification of a prospective participant in a lower tier covered transaction that it is not proposed for debarment under 48 CFR part 9, subpart 9.4, debarred, suspended, ineligible, or voluntarily excluded from the covered transaction, unless it knows that the certification is erroneous. A participant may decide the

method and frequency by which it determines the eligibility of its principals. Each participant may be, but is not, required to check the List of Parties excluded from Federal Procurement and Nonprocurement Programs.

(9) Nothing contained in the foregoing shall be construed to require establishment of a system or records in order to render in good faith the certification required by this clause. The knowledge and information of a participant is not required to exceed that which is normally possessed by a prudent person in the ordinary course of business dealings.

(10) Except for transactions authorized under paragraph 6 of these instructions, if a participant in a covered transaction knowingly enters into a lower tier covered transaction with a person who is proposed for debarment under 48 CFR part 9, subpart 9.4, suspended, debarred, ineligible, or voluntarily excluded from participation in this transaction, in addition to other remedies available to the Federal Government, the department or agency may terminate this transaction for cause or default.

C. Certification Regarding Debarment, Suspension, and Other Responsibility Matters--Primary Covered Transactions

The prospective primary participant certifies to the best of its knowledge and belief, that it and its principals:

(a) Are not presently debarred, suspended, proposed for debarment, declared ineligible, or voluntarily excluded by any Federal department or agency;

(b) Have not within a three-year period preceding this proposal been convicted of or had a civil judgment rendered against them for commission of fraud or a criminal offense in connection with obtaining, attempting to obtain, or performing a public (Federal, State or local) transaction or contract under a public transaction; violation of Federal or State antitrust statutes or commission of embezzlement, theft, forgery, bribery, falsification or destruction of records, making false statements, or receiving stolen property;

(c) Are not presently indicted for or otherwise criminally or civilly charged by a government entity (Federal, State or local) with commission of any of the offenses enumerated in paragraph (1)(b) of this certification; and

(d) Have not within a three-year period preceding this application/proposal had one or more public transactions (Federal, State or local) terminated for cause or default.

Where the prospective primary participant is unable to certify to any of the statements in this certification such prospective participant shall attach an explanation to this proposal.

D. <u>Certification at Appendix C to 32 CFR Part 25 Regarding Drug-Free Workplace Requirements</u>

(1) By signing and/or submitting this application or grant agreement, the grantee is providing the certification set out below.

(2) The certification set out below is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.

(3) For grantees other than individuals, Alternate I applies.

(4) For grantees who are individuals, Alternate II applies.

(5) Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.

(6) Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in

operation, State employees in each local unemployment office, performers in concert halls or radio studios).

(7) If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).

(8) Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules;

Controlled substance means a controlled substance in schedules I through V of the Controlled Substances Act (21 U.S.C. 812), and as further defined by regulation (21 CFR 1308.11 through 1308.15);

Conviction means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

Criminal drug statute means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

Employee means the employee of a grantee directly engaged in the performance of work under a grant, including: (i) All "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and, (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Certification Regarding Drug-Free Workplace Requirements
(Alternate I - Grantees Other Than Individuals)

The grantee certifies that it will or will continue to provide a drug-free workplace by:

(a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;

(b) Establishing an ongoing drug-free awareness program to inform employees about--

(1) The dangers of drug abuse in the workplace;

(2) The grantee's policy of maintaining a drug-free workplace;

(3) Any available drug counseling, rehabilitation, and employee assistance programs; and

(4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace.

(c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);

(d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will--

(1) Abide by the terms of the statement; and

(2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;

(e) Notifying the agency in writing, within ten calendar days after receiving notice under paragraph (d)(2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grants officer or other designee on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;

(f) Taking one of the following actions, within 30 calendar days of receiving notice under paragraph (d)(2), with respect to any employee who is so convicted--

(1) Taking appropriate personnel action against such employee, up to an including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or

(2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;

(g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

_____

_____

_____

Check if there are workplaces on file that are not identified here.

(Alternate II - Grantees Who Are Individuals)

(a) The grantee certifies that, as a condition of the grant, he or she will not engage in the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance in conducting any activity with the grant;

(b) If convicted of a criminal drug offense resulting from a violation occurring during the conduct of any grant activity, he or she will report the conviction, in writing within 10 calendar days of the conviction, to every grants officer or other designee, unless the Federal agency designates a central point for the receipt of such notices. When notice is made to such a central point, it shall include the identification number(s) of each affected grant.

IX. CERTIFICATIONS REQUIRED FOR CONTRACT AWARDS

Certifications and representations shall be completed by successful offerors prior to award. Federal Acquisition Regulation (FAR) Online Representations and Certifications Application (ORCA) is at website http://orca.bpn.gov. Defense FAR Supplemental and contract specific certification packages will be provided to the contractor for completion prior to award.

Technology Readiness Levels

Technology Readiness Level	DoD Description (Acquisition Guidebook 30 Oct 02)	Medical Description (Oct 2004)
1. Basic principles observed and reported.	Lowest level of technology readiness. Scientific research begins to be translated into applied research and development. Examples might include paper studies of a technology's basic properties.	Earliest level of technology readiness. Active monitoring of scientific knowledge base. Scientific findings are reviewed and assessed as a foundation for characterizing new technologies
2. Technology concept and/or application formulated.	Invention begins. Once basic principles are observed, practical applications can be invented. Applications are speculative and there may be no proof or detailed analysis to support the assumptions. Examples are limited to analytic studies.	Focus efforts on practical applications based on basic principles observed. Generation of scientific "paper studies" that review and generate research ideas, hypothesis, and experimental designs for addressing the related scientific issues.
3. Analytical and experimental critical function and/or characteristic proof of concept.	Active research and development is initiated. This includes analytical studies and laboratory studies to physically validate analytical predictions of separate elements of the technology. Examples include components that are not yet integrated or representative.	Research, data collection, and analysis begin in order to: test hypothesis; explore alternative concepts; identify and evaluate critical technologies and components; and research and eventual development of candidate countermeasure(s). Conduct non-clinical studies to support models based on presumed battlefield conditions.
4. Component and/or breadboard validation[1] in laboratory environment.	Basic technological components are integrated to establish that they will work together. This is relatively "low fidelity" compared to the eventual system. Examples include integration of "ad hoc" hardware in the laboratory.	Laboratory research to refine hypothesis and identify relevant parametric data required for technological assessment in a rigorous experimental design. Exploratory study of critical technologies for effective integration into candidate(s). Assess safety and efficacy utilizing animal model(s). Propose assays, surrogate markers, and endpoints to be used during non-clinical and clinical studies to evaluate and

[1] Not "validation" as defined by FDA. FDA-type validations will be done at TRL 6-8 and are needed for licensure.

Technology Readiness Level	DoD Description (Acquisition Guidebook 30 Oct 02)	Medical Description (Oct 2004)
		characterize candidate(s).
5. Component and/or breadboard validation[2] in relevant environment.	Fidelity of breadboard technology increases significantly. The basic technological components are integrated with reasonably realistic supporting elements so it can be tested in a simulated environment. Examples include "high fidelity" laboratory integration of components.	Conduct non-clinical research studies involving data collection and analysis in well-defined systems with highly characterized lots of candidate(s) produced and further development of selected candidates. Develop a robust and reproducible manufacturing process amenable to cGMP. Qualify assays for potency, purity, identity and quality. Qualify surrogate markers for efficacy in animal models
6. System/subsystem model or prototype demonstration in a relevant environment.	Representative model or prototype system, which is well beyond that of TRL 5, is tested in a relevant environment. Represents a major step up in a technology's demonstrated readiness. Examples include testing a prototype in a high-fidelity laboratory environment or in simulated operational environment.	Manufacture, release and stability test GMP pilot lots Conduct GLP safety studies Prepare and Submit IND Conduct Phase 1 clinical trial
7. System prototype demonstration in an operational environment.	Prototype near, or at, planned operational system. Represents a major step up from TRL 6, requiring demonstration of an actual system prototype in an operational environment such as an aircraft, vehicle, or space. Examples include testing the prototype in a test bed aircraft.	Conduct Phase 2 clinical trial. Establish final dose, dose range, schedule, and route of administration. Data collected, presented, and discussed with FDA at meeting (Type B). Clinical endpoints and supporting animal test plans agreed to by FDA. Complete process validation and initiate consistency lot production.

[2] Not "validation" as defined by FDA. FDA-type validations will be done at TRL 6-8 and are needed for licensure.

Technology Readiness Level	DoD Description (Acquisition Guidebook 30 Oct 02)	Medical Description (Oct 2004)
8. Actual system completed and qualified through test and demonstration.	Technology has been proven to work in its final form and under expected conditions. In almost all cases, this TRL represents the end of true system development. Examples include developmental test and evaluation of the system in its intended weapon system to determine if it meets design specifications.	Complete production & testing of consistency lots. Conduct Phase 3 clinical trials, if applicable. Submit BLA/NDA to FDA Obtain FDA approval.
9. Actual system proven through successful mission operations.	Actual application of the technology in its final form and under mission conditions, such as those encountered in operational test and evaluation. Examples include using the system under operational mission conditions.	Post licensure/approval use of product. Fulfill post-licensure commitments, if required.